IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master Docket 01-cv-12257 Subcategory 06-11337
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corporation and Baxter International, Inc.*	Civil Action No. 10-cv-11186 Judge Patti B. Saris

VEN-A-CARE'S RESPONSE TO SUN AND HAMILTON'S MOTION TO REOPEN THE JUDGMENT AND FOR A HEARING, AND MEMORANDUM IN SUPPORT

Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), Relator in this FCA qui tam action that was filed in 1995 and settled and dismissed with prejudice on October 17, 2011, submits this Response to the Motion of non-parties Sun and Hamilton to vacate the settlement and order of dismissal and for a fairness hearing pursuant to 31 U.S.C. § 3730.

I. SUMMARY OF THE ARGUMENT

Ven-A-Care agrees that a Rule 60 (b) (6) motion filed in an FCA qui tam *relator's own closed case* provides relief when the relator was *first to bring* a qui tam action and the *government* pursues an alternate remedy that deprives the relator of the fairness hearing and award required by the False Claims Act ("FCA"). See, *U.S. ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) cited by this Court in *United States ex rel. Sun, et al. v. Baxter Healthcare Corp.*, 2012 WL 3263922 at *5 (D. Mass., August 7, 2012) and by Sun and Hamilton

in their Rule 60 (b) (6) Motion. However, the Fourth Circuit's *Wagner* decision actually defeats, rather than supports, Sun and Hamilton's standing in the instant case. The *Wagner* Court held unequivocally that a *qui tam* relator is prohibited by 31 U.S.C § 3730 (b) (5)[1] from intervening, and, therefore, participating, in an FCA qui tam action *filed by another relator*. Accordingly, Sun and Hamilton do not possess the direct rights in Ven-A-Care's FCA qui tam action required for standing to bring a Rule 60 (b) (6) Motion.

While 31 U.S.C § 3730 (b) (5) provides that Sun and Hamilton have no direct rights in the Ven-A-Care FCA qui tam litigation, it also insures that their indirect rights as FCA qui tam relators could not be prejudiced by the Ven-A-Care Baxter Settlement even if, as this Court concluded, it "is not limited to drugs identified in the Ven-A-Care complaint".[2] This is because the 31 U.S.C § 3730 (b) (5) first-to-file bar precludes a second-in-time relator from bringing a qui tam action "based on the facts underlying" a pending FCA qui tam action. Ven-A-Care was the first relator to bring an FCA *qui tam* action alleging that Baxter committed Medicare and Medicaid fraud by falsely reporting inflated prices for its pharmaceutical products causing the Medicare and Medicaid programs to pay inflated reimbursement, thus creating an unlawful inducement for health care providers to purchase Baxter's products. The later Sun/Hamilton FCA qui action is barred because it alleged the same fraudulent scheme set forth in the already pending Ven-A-Care action which was resolved by the settlement. Moreover, as discussed in Section V below, the Ven-A-Care Baxter Settlement Agreement was carefully crafted to avoid encroaching on the rights of another relator.

[1] 31 U.S.C § 3730 (b) (5) provides: "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

[2] See page 10 of the Memorandum and Order granting Baxter's Motion for Partial Summary Judgment , *United States ex rel. Sun, et al. v. Baxter Healthcare Corp*., 2012 U.S. Dist. Lexis 12972 (D. Mass. January 26, 2012).

However, this Court need not reach the question of first impression of whether Rule 60 (b) (6) trumps 31 U.S.C § 3730 (b) (5) by permitting a non-party to collaterally attack the settlement and judgment in another relator's FCA qui tam action despite the statutory mandate barring that same non-party from intervening in the same qui tam action. This is because the First Circuit has found that the first-to-file bar contained in 31 U.S.C § 3730 (b) (5) restricts the Court's subject matter jurisdiction such that the Court cannot even entertain a second in time *qui tam* action alleging the same fraudulent scheme Ven-A-Care alleged ten years earlier . *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 20 (1st Cir. 2009) (threshold question in an FCA case is whether the first-to-file bar deprives the Court of subject matter jurisdiction). Also, a second in time relator's FCA *qui tam* action alleging the same fraudulent scheme as an earlier pending action is barred "'even if that claim incorporates somewhat different details.'" *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d at 32, quoting with approval, *United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227, 232-233 (3rd Cir. 1998)].

Sun and Hamilton have not shown, and cannot show, that Baxter's false price reports concerning Advate were part of a different fraudulent scheme than that previously exposed by Ven-A-Care. Accordingly they cannot meet their burdens of establishing standing under Rule 60 (b) (6) or subject matter jurisdiction under 31 U.S.C. §3730 (b) (5).

Ven-A-Care respectfully submits that the threshold, subject matter jurisdiction determinative, first-to-file issue should have been resolved in the Sun/Hamilton action and Baxter should never have been allowed to place the settlement interpretation cart before the jurisdictional horse. The "procedural pretzel" created by this mistaken juxtaposition has led to the erroneous, but serious, accusation that the Ven-A-Care Baxter Settlement Agreement may

prejudice the rights of another relator by releasing an FCA qui tam action that Ven-A-Care was not first-to-file and depriving the other relator of a 31 U.S.C. § 3730 fairness hearing. Like the settlements of the other Ven-A-Care AWP cases in which the Department of Justice declined to intervene, Ven-A-Care's Baxter Settlement was carefully crafted to avoid just such an occurrence.

Ven-A-Care also disagrees that the Advate claims were of sufficient value to provide a basis for Rule 60 (b) (6) relief or a determination that the $30 million Ven-A-Care Baxter Settlement was not fair, adequate or reasonable. In view of the extensive factual record and case law developed in this MDL, the viability of certain pharmaceutical pricing *qui tam* claims occurring after 2002 is, at best, questionable. All government reimbursement of Advate occurred after July 2003. Whether Advate added any value to an FCA settlement is made even more doubtful by the Medicare Modernization Act of 2003, which ended Medicare Part B reimbursement of anti-hemophilia blood clotting factors on the basis of 95% of AWP effective January 1, 2005 and, thereafter provided for reimbursement based on Average Sales Price ("ASP").[3] Also, CMS determined that Advate and Recombinate are to be reimbursed under a single HCPCS Code (J7192), such that reimbursement was set by averaging their AWPs (ASPs after 2004) together with other equivalent products.[4]

[3] 42 USCS § 1395w-3a; Sun and Hamilton do not allege false ASP reports.

[4] Accordingly, Recombinate and Advate, are considered together in determining a common reimbursement amount under one common HCPCS Code (J-7192) which CMS, the states and their contractors utilize in paying Medicare and, if J-Code based, Medicaid claims. See Exhibits A and B to the Declaration of James J. Breen filed in connection with this Response. These CMS publications, referenced as "Medicare Learning Network MLN Matters # MM3331" and "Change Request #3331," respectively, address the CMS billing instruction for Advate. The effective date for this instruction was July 25, 2003, the date Advate was approved as another blood-factor recombinant by the FDA.

II. PERTINENT BACKGROUND

In 1995 Ven-A-Care brought the first FCA qui tam action against certain drug manufacturers alleging that they committed Medicare and Medicaid fraud by falsely reporting inflated prices causing the Medicare and Medicaid Programs to pay inflated reimbursement, thus creating an unlawful inducement for health care providers to purchase the manufacturers' products. These actions, commonly referred to as "AWP cases", have been pursued by Ven-A-Care as a qui tam relator on behalf of Florida, Texas, California and the United States and, with Ven-A-Care's assistance, by the attorneys general of several other states.[5]

Baxter was one of the first defendants that Ven-A-Care joined in its 1995 case brought on behalf of the United States. Ven-A-Care's 2011 settlement with Baxter also resolved Ven-A-Care's Florida state qui tam action. The United States declined to intervene in and proceed with Ven-A-Care's federal FCA qui tam action against Baxter and did not join as a party to the settlement. The Florida Attorney General intervened in Ven-A-Care's Florida state qui tam action and joined in the settlement as a party.[6]

The allegations of Ven-A-Care's FCA qui tam action against Baxter explicitly included all of Baxter's drug and biological products for which Baxter reported falsely inflated prices and set forth, but was not limited to, specific examples identified in Ven-A-Care's pleadings.[7]

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[5] By way of example, early in these MDL proceedings this Court found the New York Counties were able to meet the pleading requirements of Rule 9 (b) because they had used the pricing information made available by Ven-A-Care in order to allege falsity with the requisite specificity. See footnote 8 of this Court's Memorandum and Order dated April 4, 2007 in MDL No. 1456 styled *In re AWP*.

[6] The Settlement provided for dismissals of both the instant federal court action and the companion Florida state court action of *The State of Florida ex rel. Ven-A-Care et al. v. Baxter et al.*, Second Judicial Circuit, Leon County, Florida, Circuit Civil Division, Civil Action No. 98-CA-3032C, Filed Under Seal. It does not appear that Sun or Hamilton have sought to include the Florida Attorney General in these proceedings wherein they attack the Settlement yet make no effort to explain how the requested relief can be granted unless the State of Florida is joined and the question of the Florida state court's jurisdiction over its final order of dismissal addressed.

[7] See eg, Ven-A-Care's Fourth Amended Complaint, Summary of Action, Pages 92-97 and Exhibit 6, Pages 84-103 attached as Exhibit C to the Declaration of James J. Breen filed in connection with this Response.

Among the specific examples[8] alleged by Ven-A-Care was a biological product manufactured and marketed by Baxter for the treatment of hemophilia known as blood factor VIII recombinant. The version of anti-hemophilia blood factor VIII recombinant that Baxter marketed in December 2002, when Ven-A-Care filed its Fourth Amended Complaint, was called "Recombinate" and it was so identified in the complaint. In July 2003, Baxter began to market a newer version of its anti-hemophilia blood factor VIII recombinant called "Advate".

The Department of Justice requested that Ven-A-Care's FCA qui tam action against Baxter be maintained under seal from 1995 until 2010 while it investigated Ven-A-Care's allegations against Baxter and numerous other defendants. DOJ and Ven-A-Care negotiated settlements with five manufacturers[9] while the overall action remained under seal. DOJ also joined with Ven-A-Care in the litigation and settlement of cases against three manufacturers[10] and eventually declined to intervene and allowed Ven-A-Care to proceed alone with litigation against two manufacturers.[11]

It is important to note that the instant case was part of the 1995 FCA qui tam action that Ven-A-Care brought in the United States District Court for the Southern District of Florida (referred to herein as the "Miami" case) and was primarily directed at manufacturers of infusion, IV, inhalation, injectable, and biological pharmaceuticals. Ven-A-Care also commenced a separate qui tam action in 2000 in the United States District Court for the District of Massachusetts which was primarily directed at manufacturers of self-administered drugs.[12]

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[8] Other examples included Baxter's IV fluids and IV Immunoglobulin.
[9] Glaxo, SmithKline, Aventis, Bristol Myers, B. Braun/McGaw.
[10] Abbott, Dey, and Boehringer Ingelheim
[11] Schering Plough/Warrick and Baxter. Ven-A-Care successfully negotiated settlements with both of these defendants after the Department of Justice declined to intervene.
[12] Ven-A-Care's 2000 action was also transferred to this MDL. Proceeding alone with the litigation after the United States declined to intervene, Ven-A-Care successfully secured comprehensive settlements with Teva, Mylan,

Ven-A-Care has successfully resolved all of its FCA qui tam "AWP cases" that were previously pending in this MDL, including the Baxter action at issue here. The Ven-A-Care AWP case settlements have returned approximately $3 billion to the states and federal government. The Baxter Settlement that Sun and Hamilton now ask this Court to declare invalid was patterned after other Ven-A-Care settlements of cases in which the Department of Justice declined to intervene.[13]

The widespread fraudulent scheme exposed by Ven-A-Care was so significant that investigations by the Department of Justice and HHS Office of Inspector General spanned fifteen years and were augmented by other government and Congressional inquiries, including two investigations (2001 and 2004) by the House Committee on Commerce and Energy ("HCCE") in which Ven-A-Care served as a primary witness. The information Ven-A-Care contributed to the 2001 HCCE investigation included evidence that Baxter intentionally inflated its reports of AWP and WAC for its biological products for the purpose of increasing Medicare and Medicaid reimbursement. These HCCE proceedings led to certain provisions of the Medicare Modernization Act of 2003 in which Congress ended the use of AWP in setting reimbursement for drugs and biological products and permitted CMS to reimburse Baxter's Advate and Recombinate anti-hemophilia blood factors under a common HCPS J Code 7192 based on a single array of prices (AWPs until January 1, 2005 and ASPs thereafter).

In 2005, after Ven-A-Care's FCA qui tam action against Baxter had been pending for ten years, Sun and Hamilton filed an FCA qui tam action (*United States ex rel. Sun and Hamilton v.*

Sandoz, Watson, Actavis, and Par which also included Ven-A-Care's companion state qui tam cases and, in many instances, encompassed cases brought directly by state attorneys general.

[13] An example is the $169 million Teva Settlement concluded in August 2010 in this MDL. See, *United States ex rel Ven-A-Care v. Teva, Settlement* Agreement and Release attached as Exhibit A to Document 7215, Stipulation of Dismissal.

Baxter, No. 08-CV-11200) alleging the same conduct that Ven-A-Care had long before alerted the government to; that Baxter had falsely reported inflated prices causing the Medicare and Medicaid Programs to pay inflated reimbursement, thus creating an unlawful inducement for health care providers to purchase Baxter's products. Sun and Hamilton's allegations included Baxter's anti-hemophilia blood factor VIII recombinants which, by 2005, were being marketed in two versions under the names "Recombinate" and "Advate".

Following its 2011 settlement with Ven-A-Care, Baxter successfully moved for summary judgment in the separate Sun/Hamilton qui tam case, effectively arguing that it had resolved its liability to the United States relating to allegations that it had falsely reported inflated prices for its drug and biological products causing the Medicare and Medicaid Programs to pay inflated reimbursement, thus creating an unlawful inducements for health care providers to purchase Baxter's products. In their unsuccessful opposition to Baxter's motion, Sun and Hamilton contended that the Ven-A-Care Baxter Settlement could not have released their qui tam claims because they were the first FCA qui tam relators to bring a false inflated price reporting action against Baxter encompassing the anti-hemophilia blood factor VIII recombinants marketed under the names "Recombinate" and "Advate".[14] In their Motion for Reconsideration, Sun and Hamilton contended that they had been improperly denied a fairness hearing as to Advate, but were unclear about Recombinate. Now, Sun and Hamilton have clearly limited their contentions to Advate in asking this Court to "vacate its judgment of dismissal of the *Ven-A-Care* case and the settlement between Ven-A-Care and Baxter which gave rise to that dismissal".[15]

[14] See Sun/Hamilton Memorandum in Response to Motion for Summary Judgment, pp. 2 and 15.
[15] *See* Sun/Hamilton Motion to Reopen the Judgment and for a Hearing, p. 7.

III. SUN AND HAMILTON DO NOT HAVE THE DIRECT INTEREST IN THE VEN-A-CARE BAXTER LITIGATION THAT IS A PRE-REQUISITE TO RULE 60(b) (6) RELIEF.

Rule 60(b) motions are disfavored and are properly granted only upon a showing of exceptional circumstances. *E.g., Kramer v. Gates,* 481 F.3d 788, 791-792 (D.C. Cir. 2007); *United States v. Int'l Brotherhood of Teamsters*, 247 F.3d 370, 391 (2nd Cir. 2001); *Simon v.* Navon, 116 F.3d 1, 5 (1st Cir. 1997). This is particularly true when, as here, the movants are not parties to the judgment they are seeking to set aside. *Lee v. Marvel Enterprises, Inc.*, 765 F. Supp. 2d 440, 448 (S.D. N.Y. 2011), *aff'd, Lee v. Marvel Enterprises, Inc.*, 471 Fed. Appx. 14 (2nd Cir. 2012). By its terms, standing to seek relief from a final judgment or order under Rule 60(b) is limited to "a party or its legal representative." *Ericsson v. Interdigital Communications Corp.*, 418 F.3d 1217, 1224 (Fed. Cir. 2005); *United States v. 8136 S. Dobson Street*, 125 F.3d 1076, 1082-1083 (7th Cir. 1997), *cert. denied*, *Anderson v. United States*, 523 U.S. 1111 (1998). However, some courts have made an exception to the general rule and allowed a non-party to challenge a final judgment if the non-party's rights were directly affected by the judgment. *Kem Manufacturing Corp. v. Wilder*, 817 F.2d 1517, 1520-1521 (11th Cir. 1987); *Dunlop v. Pan American World Airways, Inc.*, 672 F.2d 1044, 1052 (2nd Cir. 1982). In any event, in order to bring a Rule 60(b) motion, a person must establish that he or she has standing under that rule. *United States v. 8136 S. Dobson Street*, 125 F.3d 1076, 1082 (7th Cir. 1997), *cert. denied*, *Anderson v. United States*, 523 U.S. 1111 (1998); *Kem Manufacturing Corp. v. Wilder*, 817 F.2d 1517, 1519 (11th Cir. 1987).

Sun and Hamilton argue that *U.S. ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) supports their standing under Rule 60 (b) (6). However, a close examination of *Wagner* reveals the exact opposite. In *Wagner*, two relators, Wagner and Dehner, after agreeing to and

benefiting from the government's settlement of their earlier closed qui tam action, attempted to intervene in a different relator's qui tam action against a different defendant based upon the contention that the government's settlement of that case constituted an alternate remedy providing them with rights under 31 U.S.C. § 3730 (c) (5). The Fourth Circuit refused to allow Wagner and Dehner to intervene in the other relator's qui tam action and held: "By drafting the statute in such unequivocal language, Congress made the strongest possible statement against private party intervention in qui tam suits. The application of section 3730(b) (5) to this case is straightforward. Wagner and Dehner are persons other than the government. Therefore, the statute on its face precludes them from intervening in this action." *Wagner*, 185 F. 3d 188, 191. The *Wagner* court also found that "… an original qui tam plaintiff need not intervene in another qui tam action to vindicate his rights when the government pursues an alternate remedy…" and suggested that Rule 60 (b) (6) relief could be pursued in the relator's original action "if the relator believe that the government acted improperly." *Id.* Obviously, a relator has the requisite standing under Rule 60 (b) (6) to seek relief in their own closed case to which they are a party. However, as *Wagner* makes crystal clear, a relator is prohibited by the "unambiguous language" of 31 U.S.C. § 3730 (b) (5) from ever intervening in an FCA qui tam case brought by another relator. Therefore, a qui tam relator does not possess the direct rights in another relator's qui tam litigation that are a pre-requisite to non-party standing under Rule 60 (b) (6).

The "unambiguous" language of the "categorical prohibition" of 31 U.S.C § 3730 (b) (5) that deprives Sun and Hamilton of any rights in the Ven-A-Care qui tam action also prevents the very harm they claim to have suffered. In *Wagner* the *government* settled both of the qui tam actions in question and the court did not address the respective scopes of those settlements from a first-to-file perspective. However, in the present situation, the government declined to

intervene in either qui tam action and Ven-A-Care only settled the FCA qui tam action it was first-to-file. 31 U.S.C § 3730 (b) (5), bars Sun and Hamilton from bringing or pursuing a related action based on the same underlying facts as the earlier Ven-A-Care action resolved by the settlement. *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 15 (1st Cir. 2009); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F. 3d 1276, 1278 (10th Cir. 2004). The first-to-file bar is mandatory and, unlike the current 31 U.S.C. § 3730 (e) (4) public disclosure bar, contains no provision for waiver by the government. Therefore, Sun and Hamilton have no right to a fairness hearing concerning claims they were barred from pursuing and could not have been harmed by the Ven-A-Care Baxter Settlement.

Ven-A-Care respectfully submits that Sun and Hamilton have thus failed to meet their burden of showing a direct interest in the Ven-A-Care litigation and their Rule 60 (b) (6) Motion should be denied.

IV. THIS COURT LACKS SUBJECT MATTER JURISDICTION OVER THE SUN AND HAMILTON ADVATE FCA QUI TAM CLAIMS

As the 1st Circuit emphasized in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009), "'a goal behind the first-to-file rule' is to provide incentives to relators to 'promptly alert the government to the essential facts of a fraudulent scheme.'" *Id.* at 32. Thus, every court that has "addressed the issue [has] interpreted § 3730(b) (5) to bar 'a later allegation [if it] states all the essential facts of a previously-filed claim' or 'the same elements of a fraud described in an earlier suit….' Under this 'essential facts' standard, § 3730(b) (5) can still bar a later claim 'even if that claim incorporates somewhat different details.'" *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d at 32; *see*

United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc., 149 F.3d 227, 232-233 (3rd Cir. 1998). "[A] relator who merely adds details to a previously exposed fraud does not help 'reduce fraud or return funds to the federal fisc,' because 'once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.'" *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 378 (5th Cir. 2009).

To determine whether a *qui tam* action is barred by § 3730 (b) (5), a court need only compare the claims in the later-filed action with the claims in the original relator's complaint. *United States ex rel. Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 n.1 (10th Cir. 2004); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227, 234, 235 n. 6 (3rd Cir. 1998).

When Sun and Hamilton filed their *qui tam* action against Baxter in 2005, the Ven-A-Care Baxter *qui tam* action was clearly "pending" within the meaning of 31 U.S.C. § 3730(b)(5), and had been for approximately ten years. Also, the Sun/Hamilton action was clearly "related" to Ven-A-Care's then pending qui tam action in that the "essential facts" alleged by both Ven-A-Care and Sun/Hamilton were that Baxter falsely reported inflated prices causing the Medicare and Medicaid Programs to pay inflated reimbursement, thus creating an unlawful inducement for health care providers to purchase Baxter products. While Sun and Hamilton's allegations were directed only at claims relating to Recombinate and Advate, Ven-A-Care's allegations encompassed all of the products for which Baxter reported falsely inflated prices and further alleged examples which included the anti-hemophilia blood factor VIII recombinant product that Baxter marketed under the name "Recombinate." Ven-A-Care again specifically identified Recombinate when it last amended its complaint in December 2002 and Baxter did not begin to

market an anti-hemophilia blood factor VIII recombinant under the name "Advate" until July 2003.

Sun and Hamilton's qui tam action regarding Baxter's anti-hemophilia blood factor VIII recombinant products is precluded by the False Claims Act's first-to-file bar unless Sun and Hamilton can show that their allegations alerted the government to a different fraudulent scheme, consisting of different essential facts and different elements than the fraudulent price reporting scheme earlier alleged by Ven-A-Care. *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d at 32. At most, the Sun/Hamilton complaint merely added the "detail" that Baxter continued to report falsely inflated prices for its drugs and biological products in 2003 when it added Advate to its line of anti-hemophilia blood factor VIII recombinants. Sun and Hamilton did not allege a new fraudulent scheme different from that disclosed by Ven-A-Care's pending action that the government had been investigating for ten years.

Sun and Hamilton contend that the first-to-file bar does not apply to their qui tam action as it relates to Advate because Advate was not specifically mentioned in any Ven-A-Care complaint. Sun/Hamilton Motion to Reopen the Judgment and for a Hearing, pp. 4-5. However, Sun/Hamilton's inclusion of an additional blood-factor recombinant, Advate, is of no consequence for purposes of determining first-to-file since Sun/Hamilton's Complaint stated the same essential elements of the fraudulent scheme previously alleged by Ven-A-Care. The Third Circuit decision in *United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227 (3rd Cir. 1998), which was followed in *Duxbury*, illustrates this point clearly.

In *LaCorte*, the original relators alleged, among other things, that the defendant, SmithKline, improperly billed government health care programs separately for a "whole series of tests" that should all have been included in the price for a single automated panel of tests, a

practice known as unbundling, which resulted in the government paying more for the separately billed tests than it would have paid for the multiple-test panel. In addition to the general allegation, the original relators identified some specific unbundled tests as examples of SmithKline's fraudulent billing scheme. The late-filing relators alleged essentially the same scheme against SmithKline, but identified one specific test, gamma transpeptidase (GGT), that was not identified by the original relators or mentioned in their complaints. The trial court dismissed the late-filing relators' complaints, holding that they were barred by § 3730 (b) (5). On appeal, the late-filing relators argued that the first-to-file bar did not apply to their GGT claim because the original relators did not allege "a separate billing scheme with respect to GGT." The Third Circuit affirmed, stating that the original relators' "failure specifically to mention GGT as one of the blood tests for which SmithKline fraudulently billed the government is of no significance." *Id.* at 237. Because the late-filing relators alleged the same essential facts of the billing fraud previously alleged by the original relators, the late-relators' actions were barred by § 3730(b)(5). *Id.*

Likewise, the fact that Advate was not specifically mentioned by Ven-A-Care as one of the recombinant blood factor VIII products at issue in Baxter's fraudulent pricing scheme is of no consequence because Ven-A-Care's allegations against Baxter stated the essential facts and/or the same elements of the fraud scheme subsequently alleged by Sun and Hamilton. In other words, Sun/Hamilton's allegations regarding Advate are merely additional details of the same fraudulent scheme previously exposed by Ven-A-Care.

Duxbury has clarified any confusion in the First Circuit about the application of the first-to-file bar. For instance Judge Stearns noted that, "(t)he purpose of a qui tam action is to provide the government with sufficient notice that it is the potential victim of a fraud worthy of

investigation." *United States ex rel. Heidi Heineman-Guta v. Guidant Corp. and Boston Scientific Corp.*, U.S. Dist. Lexis 92702_ (D. Mass. 2012). "(O)nce the whistle has sounded the government has little need for additional whistle-blowers." *Id*.; quoting, *United States ex rel. Batiste v. SLM Corp.*, 740 F.Supp.2d, 104; affirmed, *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011).

Nor does this Court's pre- *Duxbury* ruling in *United States ex rel. Ven-A-Care v. Abbott Labs., Inc.*, 2008 WL 2778808 (D. Mass. July 15, 2008), support Sun and Hamilton's contention that the first-to-file bar does not preclude their Advate claim.[16] In the *Abbott* litigation, Ven-A-Care, was the relator in both cases and the issue was whether the drug Erythromycin was encompassed by Ven-A-Care's earlier Miami case or later Massachusetts case.[17] The Court noted in *Abbott* that the two Abbott cases involved different classes of drugs marketed by different Abbott divisions. Specifically, Ven-A-Care's Miami case involved intravenous drugs, injectables, inhalation drugs and biological products, which are generally administered by physicians or other health care professionals. Ven-A-Care's Massachusetts case involved Erythromycin, which is primarily a self-administered drug that was marketed by Abbott's pharmaceutical products division.

The facts in the present case lead to the opposite first-to-file conclusion than did those in *Abbott*, especially in light of the more recent *Duxbur*y decision. Advate is a blood factor VIII recombinant product, manufactured by Baxter's biological division and used to treat hemophilia, just like the Recombinate identified as an example by Ven-A-Care. Also, both Advate and

[16] This Court's decision in *United States ex rel. Ven-A-Care v. Abbott Labs., Inc* occurred a year before the decision of the 1st Circuit in *Duxbury*, relying on the 3rd Circuit *LaCorte* decision and further clarifying the law with respect to the first-to-file bar.

[17] The earlier FCA qui tam action at issue in Abbott, filed in the United States District Court for the Southern District of Florida, is the same Ven-A-Care qui tam action as that at issue here as both Abbott and Baxter were defendants in Ven-A-Care's 1995Miami action.

Recombinate are biological products typically administered by healthcare professionals as were the other drugs and biologicals encompassed by Ven-A-Care's original federal case filed in Miami against Baxter. Accordingly, Advate and Recombinate are both encompassed by Ven-A-Care's first-in-time Miami case which was directed at such Baxter infusion drugs. The Court's ruling in *Abbott*, like the binding precedent of *Duxbury*, calls for the dismissal of the Sun/Hamilton action pursuant to 31 U.S.C. § 3730 (b) (5).

Ven-A-Care's AWP cases ratify the wisdom of *Duxbury's* focus on the False Claims Act's intent to encourage relators to move swiftly to alert the government to their allegations. Ven-A-Care was the first qui tam relator, and first litigant for that matter, to bring an "AWP" type pricing case and has retuned billions of dollars to the state and federal treasuries since 1995. Ven-A-Care succeeded because it proceeded expeditiously, diligently and responsibly, devoted tremendous resources for the benefit of the government and acted reasonably to resolve its FCA qui tam actions through settlements. Now, Sun and Hamilton seek a construction of the first-to-file bar that, contrary to *Duxbury*, encourages later opportunistic qui tam relators to simply pick NDCs that happen to not appear in a Ven-A-Care AWP complaint, and then launch attacks on the Ven-A-Care AWP settlements. Ven-A-Care respectfully submits that such a result is not permitted by 31 U.S.C § 3730(b) (5) and the Sun/Hamilton Advate claim is barred.

V. THE PLAIN LANGAUGE OF THE VEN-A-CARE BAXTER SETTLEMENT PRECLUDES ITS APPLICATION TO PENDING QUI TAM CLAIMS FIRST BROUGHT BY ANOTHER RELATOR

At the time of the settlement of this action, Ven-A-Care, Baxter, the Department of Justice, and Sun/Hamilton were fully aware that issues about the viability of the Sun/Hamilton Advate claims would remain unresolved, including whether they were precluded by the FCA's

first-to-file bar due to Ven-A-Care's first-in-time action. Ven-A-Care respectfully submits that the language of its Settlement Agreement and related documents must be reasonably construed in the context of applicable law, including *Duxbury's* interpretation of the first-to-file bar, and taking into consideration the simple fact that the parties accepted the uncertainty surrounding the Advate claims as part of their bargain.

Against this backdrop, the settlement was entered by Baxter, the State of Florida, Ven-A-Care for its own behalf, and Ven-A-Care as a qui tam relator acting on behalf of the United States. Importantly, the settlement expressly provided, in Section I ("Parties") that the United States was not a party and Ven-A-Care acted for the United States "with respect to such qui tam claims as the Relator has pled on their behalf". The Settlement also defined the "Covered Conduct" at Paragraphs E and F of Section II consistently with the allegations Ven-A-Care had pled in its FCA qui tam action, defined as the "Federal Qui tam Proceedings". Like the allegations in Ven-A-Care's complaints (which are listed at Paragraph B), the Covered Conduct encompasses all of Baxter's drug and biological products for which it reported false inflated prices. As *Duxbury* and *LaCorte* make clear, it was not necessary for Ven-A-Care to have identified Advate in its complaints for it to fall within the scope of Ven-A-Care's action for first-to-file purposes. The Covered Conduct settled by Ven-A-Care was no more than it pled in its first in time FCA qui tam action.

The congruence between the allegations in Ven-A-Care's FCA qui tam action and the description of Covered Conduct in its settlement shows that Ven-A-Care only settled claims of the United States encompassed by its earlier in time action. However, the settlement contains further protections against the theoretical possibility that the definition of Covered Conduct

could be construed more broadly than Ven-A-Care's first in time FCA qui tam action. Those protections appear in the Release at Paragraph 7 and the Severability Clause at Paragraph 13.

The Release at Paragraph 7 contains specific language expressly limiting the release Ven-A-Care gave on behalf of the United States as follows: "…including, with respect to the Relator, to the extent it is capable under the law all *qui tam* claims brought on behalf of the United States in the Federal Qui Tam proceedings…" The words "capable under the law" must be read in conjunction with the provision of Paragraph 13 which states "This Agreement shall be governed by the laws of the United States". Obviously, the laws of the United States include the False Claims Act's first-to-file bar which must be applied to the words "brought on behalf of the United States in the Federal Qui Tam proceedings". If one accepts the theoretical proposition that Sun and Hamilton were first to file as to the Advate claims, then, in light of 31 U.S.C. § 3730 (b) (5), one must also conclude that they were not claims Ven-A-Care "brought on behalf of the United States in the Federal Qui Tam proceedings" or that it was "capable under the law" of releasing on behalf of the United States. Accordingly, if Ven-A-Care did not bring a particular qui tam claim for the United States, it did not release the claim on behalf of the United States. Also, the Consent of the United States and agreed form of the Order of Dismissal with Prejudice each specifically incorporate the limitations set forth in the Settlement Agreement and provide only for the dismissal of Ven-A-Care's qui tam action and no other relator's qui tam claims or action.

Even if the Settlement Agreement had failed to include the protections discussed above, it could not be applied in a manner that deprives another relator of a fairness hearing. Paragraph III.20 of the Settlement Agreement contains a severability clause which states in pertinent part:

> "If any provision of this Agreement, or the application thereof, shall for any reason or to any extent be construed by a court of competent jurisdiction to be invalid or

> unenforceable, the remainder of this Agreement, and application of such provision to other circumstances, shall remain in effect and be interpreted so as best reasonably to effect the intent of the Parties."

Accordingly, even if certain language of the Agreement could otherwise reach the subject matter of an FCA qui tam action that another relator was first-to-file and was thus entitled to a fairness hearing, the Agreement must be construed to simply exclude that subject matter and otherwise remain valid and enforceable.

As this Court noted in granting Baxter's Motion for Partial Summary Judgment, "[t]he terms of the settlement agreement should be construed by applying 'the same basic rules that govern the interpretation of ordinary contracts' such that 'terms within [the] contract are accorded their 'plain, ordinary, and natural meaning.'".[18] It is fundamental that the interpretation of a contract that "gives reasonable, lawful and effective meaning to all the terms is preferred to an interpretation which leaves a part unreasonable, unlawful or of no effect" and "specific terms and exact terms are given more weight than general language..." See, § 203, Restatement of Contracts (Second). Ven-A-Care's construction and interpretation of the Settlement Agreement is clearly reasonable and consistent with the applicable provisions of the False Claims Act. It is also consistent with the bargain that Ven-A-Care and Baxter reached knowing that questions about the viability of the Sun/Hamilton action remained unanswered and that this uncertainty was simply part of the deal.

It is now obvious that, at the time it entered the Settlement Agreement, Baxter intended to immediately assert that the settlement encompassed the Sun/Hamilton claims regardless of the FCA qui tam action in which they were first filed. Baxter thus knowingly invited the potential

[18] Page 9 of the Memorandum and Order granting Baxter's Motion for Partial Summary Judgment , *United States ex rel. Sun, et al. v. Baxter Healthcare Corp*., 2012 U.S. Dist. Lexis 12972 (D. Mass. January 26, 2012), quoting from *Nault v. United States*, 517 F.3d 2, 4 (1st Cir 2008).

argument that Sun and Hamilton were deprived of a fairness hearing if it were determined that they were first-to-file as to Advate. Baxter could have avoided this problem simply by requesting a fairness hearing in the Sun/Hamilton action before the consummation of the settlement and disbursement of the settlement funds and before the Court approved the settlement and dismissed the Ven-A-Care action. Under the circumstances and plain language of the Agreement, the settlement should simply be construed not to extend to such portion of the Sun/Hamilton action, if any, that the Court concludes Sun or Hamilton was first to file pursuant to 31 U.S.C. § 3730 (b) (5).

Ven-A-Care respectfully submits that the Court should not invalidate the Ven-A-Care Baxter Settlement.

VI. CONCLUSION AND REQUEST FOR RELIEF

For the reasons stated, Ven-A-Care requests that the Court find that Sun and Hamilton have failed to make the requisite showing of an interest in the Ven-A-Care litigation to entitle them to relief pursuant to Rule 60 (b) (6) and deny Sun and Hamilton's Motion to Reopen the Judgment and For a Hearing.

In the alternative, if the Court finds that Sun and Hamilton are entitled to relief under Rule 60 (b) (6), Ven-A-Care requests that the Court conduct an evidentiary hearing as to the fairness, adequacy and reasonableness of the Ven-A-Care Baxter Settlement and that it enter a finding that the settlement was fair, adequate and reasonable and that the Order of Dismissal With Prejudice should not be vacated or, if already vacated, should be reinstated.

Respectfully submitted,

JAMES J. BREEN
Florida Bar No. 297178
The Breen Law Firm, P.A.
5755 North Point Parkway
Suite 260
Alpharetta, Ga. 30022
(678) 735-5052
(770) 740-9109 (Fax)

C. JARRETT ANDERSON
Texas Bar No. 00796124
Anderson LLC
1409 Wathen Ave.
Austin, Texas 78703
(512) 469-9191
(512) 532-0585 (Fax)

RAND J. RIKLIN
(TX Bar No. 16924275)
JOHN CLARK
(TX Bar No. 04287000)
Goode Casseb Jones
Riklin Choate & Watson, P.C.
P.O. Box 120480
San Antonio, Texas 78212
(210) 733-6030
(210) 733-0330 - Fax

By: /s/ James J. Breen
James J. Breen
(FL Bar No. 297178)

CERTIFICATE OF SERVICE

I hereby certify that I, James J. Breen, caused a true and correct copy of the foregoing to be served on all counsel of record electronically on October 5, 2012, pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LEXIS File & Serve electronic filing service.

By: /s/ James J. Breen

James J. Breen